INFOSYS SERIALIZATION TRACK AND TRACE SOLUTION SUITE

Product authentication and traceability is the need of the hour in the fight against product counterfeiting, reimbursement fraud, diversions, and medication errors. Governments across the globe are enabling strict legislations to ensure accurate and reliable drug tracking and authentication at each node of the supply chain, right up to the patients. Pharmaceutical organizations would be served better to treat serialization projects as benefit-driven programs, rather than mere compliance-mandated investments. This way, they can derive substantial returns from lower recall costs and ensure improved visibility across a secured supply chain.

Business challenges in implementing a serialization solution

- Standards and guidelines are constantly evolving and serialization programs need to be flexible
- Serialization covers the entire supply chain and involves integration of various technologies and entities (like legacy systems, core ERP, and cloud), which makes the solution complex
- Timelines to implement serialization programs can get extended from 3–6 years, and it is imperative to have rigorous control and governance mechanisms to ensure that the results are visible to the leadership of the organization
- Amount of data generated by serialization is huge and is estimated to double every 15 months; managing such volumes can get complicated
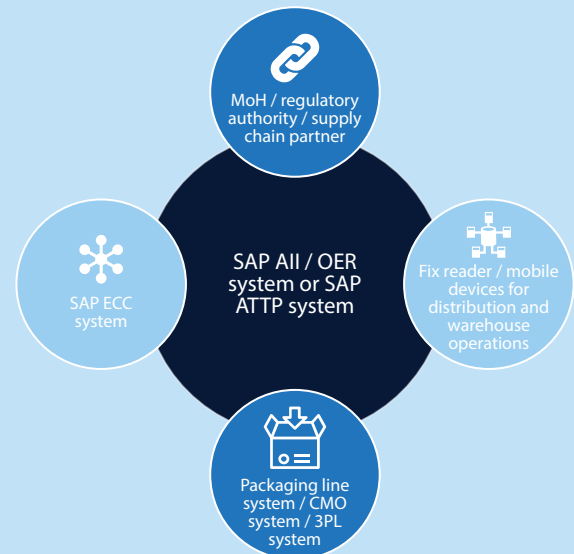
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Providing end-to-end tracking of the pharmaceutical supply chain

Active ingredients	Inactive ingredients	Finished drug	National and regional wholesalers	Smaller wholesalers	Hospital & pharmacies	Patients

Infosys Serialization Track and Trace Solution Suite

We have over seven years of experience in implementing serialization programs for major pharmaceutical companies, resulting in an extensive understanding of operational challenges, technologies, and compliance requirements. The Infosys Serialization Track and Trace solution suite uses SAP components like SAP ECC, SAP Auto-ID Infrastructure (AII), SAP Object Event Repository (OER), SAP Event Management (EM), SAP ATTP (Advanced Track and Trace for Pharmaceuticals), SAP PI, and SAP ITS Mobile.

SAP AII / OER system or SAP ATTP system

- MoH / regulatory authority / supply chain partner
- SAP ECC system
- Fix reader / mobile devices for distribution and warehouse operations
- Packaging line system / CMO system / 3PL system

Salient features of Infosys Serialization Track and Trace solution suite

- **Accelerator for packaging line solution:** Ready-to-use interface mapping templates that recognize all file formats for the data exchange between the packaging line solutions and SAP ATTP (Advanced Track and Trace for Pharmaceuticals) or SAP Auto-ID infrastructure (AII)

- **Accelerator to speed up configuration of SAP ATTP or SAP AII / OER:** Improved business process mapping, solution articulation, and ready-to-use templates for regulatory reporting speed up the implementation and integration of supply chain processes using preconfigured solutions

- **Accelerator for migration to SAP ATTP:** Predesigned solution architecture for all possible variations of the existing serialization system setup reduces the time and cost for scope, seek, and conceptual design, and ensures seamless migration to SAP ATTP

- **Accelerator for testing:** Test tools for hierarchy upload and business document creation create serialized data / hierarchies and transactional data documents, thus reducing the time and cost of testing and training

- **Industry best practices:** A talent pool of subject matter experts with experience in global implementation of serialization and sound knowledge of regulatory systems and compliance mandates, including FDA, TGA, GxP, and 21 CFR Part 11

- **Consolidated legal, regulatory guide:** Compilation provides a summary of the legal and regulatory framework proposed by prominent early adopters of serialization, like USA, China, Brazil, France, India, South Korea, etc. Our guide also provides information on mandates that have to be adhered to by various stakeholders, to ensure regulatory compliance

Business benefits

- Estimated reduction of 30% in implementation timelines
- Ability to preconfigure independent of the client's infrastructure
- Easy integration with enterprise ecosystems
- Single-point access to skills required in databases, packaging line integration, distribution line integration, device integration, and mobile-tracking

For more information, contact askus@infosys.com

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